Implementing the Pesticide Registration Improvement Act-Fiscal Year 2008

Fifth annual report. Report release date: March 1, 2009.

The Consolidated Appropriations Act of 2004 established a new system for registering pesticides, called the Pesticide Registration Improvement Act, or PRIA. The new section 33 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), PRIA created a registration service fee system for applications for specified pesticide registration, amended registration, and associated tolerance actions, which set maximum residue levels for food and feed. Under PRIA, fees are charged for covered applications received on or after March 23, 2004, and for certain pending applications received before that date. The Environmental Protection Agency (EPA) is required to make a determination on the application within the decision times specified. The fee system was authorized until September 30, 2010. Due to the efforts of the PRIA Coalition of industry, trade associations, and public interest groups, PRIA was reauthorized on October 9, 2007 effective retroactively to October 1, 2007, the beginning of Fiscal Year 2008. The Pesticide Registration Improvement Renewal Act (PRIA 2) authorized the fee system to September 30, 2012.

Under Section 33(k) of PRIA, EPA is required to publish an annual report describing actions taken under this section during the past fiscal year. The report must include several elements, including a review of the progress made in carrying out the Agency's obligations under the Act, a description of the staffing and resources associated with the review of and decision-making on applications, and a review of its progress in meeting the reregistration and tolerance reassessment timeline requirements. PRIA 2 increased these reporting requirements to include information on electronic label review, a review of applications under section 3(c)(3)(B), and information on registration review that includes resource expenditures and recommendations for process improvements.

This fifth annual report covers Fiscal Year 2008 -- October 1, 2007 through September 30, 2008, the first Fiscal Year under the PRIA 2 and this report focuses on its implementation and impact. As a result of PRIA 2, the Agency was required to revise some processes and develop new ones and to modify its databases to meet new reporting requirements.

PRIA 2 Enhancements in Application In-Processing

Previous annual reports (2004, 2005, 2006 and 2007) described the steps the Agency undertook to implement PRIA. When PRIA 2 became effective, the Agency modified its in-processing procedures and processes. PRIA 2 increased the fee categories from 90 to 140 and changed payment procedures and how applications are screened upon receipt.

Front-End Processing and Screening Procedures - FY 2008

When PRIA 1 was implemented in 2004, the Agency established an intra-agency workgroup that interpreted the 90 PRIA 1 fee categories to help applicants and the Agency consistently place each application in the appropriate PRIA category. These PRIA registration categories reflected the types of applications the Agency may receive and for which Congress has established a fee and a time frame. The time frame, or decision review time, is the amount of time the Agency is expected to take to review the application and reach a regulatory decision. The intra-agency workgroup modified these interpretations for PRIA 2 and developed interpretations for the additional 50 fee categories. PRIA 2 revised or expanded the description of some PRIA 1 categories, requiring modifications in the Agency's interpretation of these categories. The PRIA 2 interpretations are available on the pesticides Web site on the Fee Determination Decision Tree. The Agency enhanced its tracking system, Pesticide Registration Information System

(PRISM), to track both the PRIA 1 and PRIA 2 fee categories and time frames. Reports were developed or modified to monitor the status of PRIA 2 and remaining PRIA 1 applications and decisions.

The Agency elected to invoice applicants instead of requiring payment at submission of an application under PRIA 1 because applicants were unfamiliar with the fee categories. Under this system, teams of EPA experts from the three registering divisions (conventional chemical, biopesticide, and antimicrobial pesticides) screened all incoming applications to determine whether they were subject to PRIA, assigned the application to a PRIA category if appropriate and conducted a cursory screen of the application. The applicant was then invoiced for the amount with payment due within 45 days.

Certain provisions in PRIA 2 required the Agency to substantially modify this procedure. Under Section 33(b)(2)(D), the fee is due upon submission of the application. Section 33(b)(2)(F) directs the Agency to reject any application submitted without the required registration service fee. Consequently, the invoicing system was discontinued except when an additional payment is required. A portion of the fee, 25%, is non-refundable once an application is submitted per Section 33(b)(2)(G). If any fee is unpaid 30 days after the fee is due, under Section 33(b)(2)(H), it shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code. A certification of payment is required with the application. Credit card or wire transfer payments can be made using the Treasury Department's pay.gov system, which provides an acknowledgement of payment. This acknowledgement of payment or a photocopy of a bank check serves as a certification of payment.

Since applicants have to identify the appropriate fee and pay it in advance of submitting an application (pre-payment) or upon submission to EPA, the Agency developed the Fee Determination Decision Tree and modified its tracking system, PRISM, to track payments and then match payments with applications, instead of with invoices. The Fee Determination Decision Tree is a tool that, through a series of questions and answers, allows pesticide registration applicants to identify an appropriate fee category and fee. Payment information and a link to pay.gov for credit card and wire transfer payments are provided on the Decision Tree Web site. Once an application is received, the expert teams established under PRIA 1 screen the application and assign a PRIA 2 fee category. If the appropriate amount is not received, the Agency invoices the applicant for the unpaid portion, typically within 48-72 hours of receipt of an application.

The Agency treated the first quarter of FY 2008 as a transition period to provide enough time for applicants to become acquainted with the new payment procedures, and continued to send invoices requesting payment of the appropriate PRIA registration service fee if certification of payment was not received with the application. In November 2007 the Agency held a PRIA 2 workshop during which payment requirements were described and instructions provided on how to submit payment. At this workshop the Agency announced that it would stop invoicing, and would require pre-payment beginning January 2, 2008. Beginning on that date the Agency implemented a policy of not placing an application into the registration and review process if it did not contain certification of payment. The Agency would contact the registrant informing them that certification of payment was required together with the application. If certification of payment was not received within 15 days, the Agency would reject the application, and invoice the registrant for 25% of the appropriate fee. Nine applications were rejected in FY 2008 for failure to submit the appropriate fee.

21 Day Initial Content Screen

The cursory screen that the expert teams conducted under PRIA 1 had to be modified to implement Section 33(f)(4)(B), "Completeness of Application". This section directs the Agency, not later than 21 days after receiving an application and the required registration service fee, to conduct an initial screening of the contents of the application. In conducting this screen, the Agency must determine (1) whether the applicable registration service fee has been paid; or (2) at least 25 percent of the applicable registration service fee has been paid and the application contains a waiver or refund request for the outstanding amount and documentation establishing the basis for the waiver request; and (3) that the application contains all the necessary forms, data, and draft labeling, formatted in accordance with guidance published by the Agency. If the application fails the screen and can not be corrected by the applicant

within the 21 day period, the Agency will reject the application.

The Agency phased in this screen. During the November 2007 PRIA 2 workshop, the Agency described its short term procedures for conducting this screen and its long term plans. Screening requirements were defined and a rejection process was developed by an intra-agency workgroup. Initially, registering divisions assigned individuals or formed a team to conduct the screen of applications assigned to the division. A screening worksheet was developed, tested and made publicly available on the pesticides Web site. This screen began in January 2008, and during FY 2008, the Agency rejected 14 applications.

For the long term and to assure consistency across the pesticide program, the initial screen will be conducted by a contractor followed by a review of the results by Agency employees. Based on the experience gained during FY 2008, specifications were developed for this contractor support with a pilot to be conducted at the beginning of FY 2009.

The initial data screen for compliance with the Agency's formatting guidance, PRN 86-5 is a component of the 21 day initial content screen. The Agency originally enhanced its existing data management contract for the initial data screen in FY 2004 to reduce study processing time to 10 days and ensure that complete data packages are ready to enter the review process at the beginning of the decision review period if the applicant has correctly formatted the data submission. In FY 2007, the study processing time was 4.87 days. In FY 2008 the average study processing time was 7.6 days. During FY 2008, a new contractor began to conduct the 86-5 screen and the average study processing time increased when this transition occurred which increased the yearly average study processing time. This contractor will conduct the initial 21 day content screen in FY 2009.

Funds Management and Utilization

Section 33(c) of PRIA established the Pesticide Registration Fund. Congress established this fund in the Treasury of the United States to carry out the provisions of PRIA. All registration service fees received by EPA are deposited in this fund, and expenditures from the fund can cover the costs associated with review and decision-making for applications for which registration service fees have been paid. As of October 2007, fees are deposited into an account maintained by the U.S. Bank in St. Louis, Missouri, which informs the Agency when a payment is received. The date of payment receipt triggers the start of the PRIA decision review period, or time frame. The Agency has been informed of the receipt of a payment within an average of 7.2 days of receipt by the bank, and the Agency automatically sends an acknowledgment of payment to those applicants with an e-mail address on file.

The Agency encourages applicants to pay their fees by credit card or wire transfer using the Treasury Department's pay.gov system. These payments are more efficiently deposited with the U.S. Bank. In FY 2008 payments totaling $ 4,780,737 were made through pay.gov for 959 decisions. This represents 56% of the total number of actions for which payment was received.

Under PRIA 1, EPA notified applicants when a payment was 45 days overdue for all PRIA fee categories except Fast Track applications (because of the short time frames for these actions). The notification provided the applicant 75 days to forward payment before the application was withdrawn by the Agency. In FY 2008 the Agency sent 59 such letters, resulting in 40 payments (totaling $400,312), 11 withdrawn applications, 4 fee waivers, and 4 determined to be secondary actions requiring no fee. These applications were received prior to PRIA 2's effective date. Applications received on or after October 1, 2008 are covered by PRIA 2's payment provisions: if payment is not received, the Agency rejects the application.

Communications and Outreach

Communications and outreach efforts in FY 2008 focused on the differences between PRIA 1 and 2 and their implementation. The Agency gave an overview of PRIA 2 during an October 17, 2007 Pesticide Program Dialogue Committee (PPDC) meeting. As required under PRIA 2, Section 33(b)(3)(A), a *Federal Register* notice was published on October 30, 2007, (within 30 days of PRIA 2's effective date) announcing the new fee schedule. These fees were increased per Section 33(b)(6) by 5% effective October 1, 2008, with the publication of another *Federal Register* notice on August 5, 2008.

The Agency held a public workshop on November 27, 2007, in which the Agency gave an overview of PRIA 2 and discussed changes in payment procedures and the 21-day content screen. Questions specific to applications were addressed in the antimicrobial, biopesticide and conventional chemical breakout groups.

The Agency's PRIA Webpage was revised for PRIA 2, and to help applicants identify their application's fee, the Agency developed the PRIA Fee Determination Decision Tree. As a result of user feedback, the Decision Tree was modified. PRIA time frames were incorporated and the fee category descriptions or interpretations were further enhanced in October 2008. Guidance on small business fee waivers , IR-4 exemptions, inerts, payment procedures, and the 21 day initial content screenwere posted. Through the PRIA Website, the public can submit questions regarding PRIA implementation. Questions are typically answered within 24 hours. Questions are also addressed by registration Ombudsmen. The Ombudsmen help applicants with issues related to identifying an application's fee and fee category, the implementation of PRIA 2, the registration process, and completing application forms.

Agency staff discussed PRIA 2 implementation during the Chemical Producers and Distributors Association Registration Workshop, meetings of CropLife America and the Consumer Specialty Products Association, with State and EPA Regional staff at the Pesticide Regulatory Education Program, and with the Armed Forces Pest Management Board. EPA provided updates on the status of PRIA actions received and summary statistics during meetings of the Agency's Federal Advisory Committee, the Pesticide Program Dialogue Committee (PPDC), PPDC Process Improvement Workgroup and meetings with the PRIA Coalition, composed of industry, trade associations, and public interest groups. EPA also has quarterly meetings with the Biopesticide Industry Alliance to discuss PRIA and other common issues and with the United States Department of Agriculture (USDA) IR-4 program, and monthly teleconferences with USDA's Animal Health Inspection Service and the Food and Drug Administration on Plant Incorporated Protectants.

Registration Program Workplans

The Agency's pesticide registering divisions continue to make their processes more transparent by providing additional information to the public on its Registering Pesticides Internet site such as workplans, schedules, and guidance. The multi-yearworkplan for new conventional chemical actions and new uses under PRIA is updated quarterly. These updates reflect new actions received under PRIA, actions completed, and changes to schedules. For a majority of the new chemical and new use actions listed, the time frame in which the Agency expects to complete its registration decision is shorter than that specified by PRIA. When possible, requests for new uses submitted by USDA's Inter-Regional Research Project Number 4 (IR-4) program that are also being requested by registrants are merged to allow one risk assessment. Additional economies and time-savings were achieved where possible by folding new use assessments into assessments conducted for reregistration. As they are registered, the Agency continues to post risk assessments for new conventional pesticides to aid registrants with future submissions. Human health and ecological risk assessments are attached to the new active ingredient fact sheets.

The FY 2008 and 2009 workplans for biopesticides are available on the Agency's pesticides website. The biopesticides workplan is updated at least once a quarter to reflect completed actions and changes to the schedule. Biopesticide Registration Action Documents (BRAD), posted on the Web for all new biopesticide decisions, give the basis for the Agency's decision including a review of the studies submitted to support the registration.

The Antimicrobial's FY 2008 workplan is published on the Web and the FY 2009 schedule for new antimicrobials and new antimicrobial uses has also been published.

Financial Overview

During Fiscal Year 2008, the Agency received $17.1 million in new registration service fees and after subtracting $1.3 million in refunds (overpayments and withdrawals), net receipts were $15.8 million. A balance of $10.3 million was carried forward from FY 2007. From this total of $26.1 million, the Agency spent approximately $17.2 million, carrying the remaining balance of $8.9 million forward to FY 2009. A balance is carried forward to fund personnel and contractor support for applications with multi-year time frames and for which some or most of the work is performed in the next fiscal year. Without a balance at the beginning of a fiscal year, staff would have to be reassigned from PRIA work until more fees were collected. This would disrupt the process and possibly result in missed PRIA deadlines. Spending increased by 14% in FY 2008, compared with FY 2007. Consequently, the end of year remaining balance decreased by 14% in FY 2008 from FY 2007. The major factor that increased spending in FY 2008 was the 200% increase in set-asides (new statutory mandates in PRIA 2) for worker protection, partnership grants, and the Pesticide Safety Education Program.

Under Section 33(c), interest earned and added to the PRIA Registration Fund is available to the Agency for spending. Interest in FY 2008 totaled $10,045.

Agency's FY 2004 through FY 2008 Expenditures from the Pesticide Registration Fund

For	FY 2004 Expenditures (in thousands)	FY 2005 Expenditures (in thousands)	FY 2006 Expenditures (in thousands)	FY 2007 Expenditures (in thousands)	FY 2008 Expenditures (in thousands)
Payroll	$2,535.3	$7,898.2	$5,819.8	$7,111.6	$7,556.4
Contracts	$1,591.3	$2,228.8	$4,013.1	$6,979.5	$7,168.1
Worker Protection	$430.0	$750.1	$750.0	$750.0	$2,250.0
Other Expenses	$455.8	$274.3	$221.6	$302.7	$205.8
Total	$5,012.5	$11,151.4	$10,804.5	$15,143.8	$17,180.3

In FY 2008, both data review output through contracts and payroll costs increased modestly compared with FY 2007. Payroll expenditures increased to $7.6 million in FY 2008 from $7.1 million spent in FY 2007. Expenditures on contracts increased to approximately $7.2 million in FY 2008, compared with $7.0 million in FY 2007. As a result the balance between payroll and contract expenditures changed little from 2007 to 2008 (with payroll at 44% of expenditures in FY 2008 compared with 47% in FY 2007, and contracts at 42% in FY 2008 and 46% in FY 2007). Although increasing in absolute terms, both contracts and payroll were down as a percentage of total expenditures from the Registration Fund in FY 2008 due to the increase in worker protection and other mandated programs. In addition to funds from the PRIA Pesticide Registration Fund, the registration program spent about $40.1 M from appropriated funds.

The mandated programs under PRIA increased from $0.75 million in FY 2007 to $2.25 million in FY 2008 under PRIA 2. These mandates included worker protection ($1.0 million), partnership grants ($0.75

million), and the Pesticide Safety Education Program ($0.5 million). The percentage of expenditures going to the mandatory programs grew from 5% in FY 2007 to 13% in FY 2008. The Agency also continued to invest in upgrading its information management systems to track compliance with the PRIA review time frames, to meet reporting requirements, and to implement PRIA 2 requirements. Other funds went primarily to pay for *Federal Register* printing costs associated with PRIA registrations.

Waivers of and Exemptions from Registration Service Fees

Section 33(b)(7) of PRIA authorizes the Agency to reduce or exempt the registration service fee under certain specified situations. Under the original PRIA, a fee for a qualified small business could be waived up to 100%, while under PRIA 2, the maximum waiver became 75% of the fee. A portion of all fees, 25%, is non-refundable. The Agency developed and posted on the Web guidance for small businesses on applying for a fee waiver to reduce a registration service fee. Section 33(b)(7) also provides an exemption from a registration service fee for applications from Federal or State agencies and for applications solely associated with a tolerance petition submitted in connection with the Inter-Regional Project Number 4, which is in the public interest. Under PRIA 1, applications associated with IR-4 tolerance petitions received a 100% waiver.

In FY 2008, the Agency granted 293 fee waivers and exemptions and denied 10 as shown in the following table. The remaining 16 were pending review at the end of the fiscal year. The 100% small business waivers listed were for actions submitted prior to the effective date of PRIA 2.

Waiver Type	Received	Granted	Denied	Wighdrawn
100% Small Business	11	9	1	0
75% Ultra Business	184	176	5	0
50% Small Business	78	64	4	0
IR-4	42	40	0	0
Minor Use	0	0	0	0
Federal State	4	4	0	0
Total	319	293	10	0

The average number of days required to grant a fee waiver in FY 2008 was consistent with the time required in FY 2007. The average amount of time it took the Agency to deny a fee waiver is greater due to the increased time that the Agency took in an attempt to resolve the issues. The time to deny a fee waiver ranged from 15 to 61 days and the average in each quarter is shown below. There were no denials in the 2nd quarter FY08.

Average Number of Days to Process Fee Waivers in a Quarter, FY 2008		
Quarter	**To Grant**	**To Deny**
1st Q	23	41
2nd Q	25	--
3rd Q	22	52
4th Q	22	34

The total fees waived and exempted in FY 2008 was $7.85 million, which was consistent with past fiscal years except for FY 2007 ($11.4M). The majority, 84% of these waived or exempted fees were as a result of IR-4 exemptions, and approximately 15% were small business fee waivers. The total amount waived for small businesses during FY 2008 was lower than in past fiscal years, probably due to the reduction in the maximum that can be waived under PRIA 2. In most fiscal years, the greatest amount waived or exempted was for applications solely associated with an IR-4 tolerance petition. Few requests were received to exempt federal and state agencies from fees.

Amount in Fee Waivers and Exemptions by Fiscal Year and Type (in $1,000)				
Fiscal Year/Type	Small Business	IR-4	Federal/State Agencies	Total
FY 2004	$3,699	$2,745	-----	$6,444
FY 2005	$3,006	$5,460	$15	$8,481
FY 2006	$1,497	$4,226	$40	$5,763
FY 2007	$2,162	$8,342	$924	$11,428
FY 2008	$1,232	$6,592	$28	$7,853

Fee Reductions

Section 33(b)(8)(C) authorizes EPA to issue discretionary refunds, including instances where the Agency had completed portions of the review of an application before March 2004. For fees required for pending new active ingredients and for applications pending prior to March 2004 where the registrant has offered to pay the registration service fee voluntarily, the Agency applied this refund provision as a credit toward the registration application service fee. In past fiscal years, the amount in registration service fees that were reduced declined each year from $3.7 million in FY 2004 to approximately $3,500 in FY 2007. In FY 2008, no voluntary payments were received.

Reregistration and Expedited Processing Fund

In FY 2008, the amount of money from the Reregistration and Expedited Processing Fund (maintenance fees or yearly registration renewal fees) used to carry out inert ingredient reviews under section 4(k)(3) totaled $0.9 million. This supported 6.6 work years and included $0.05 million in contract funds. An additional $1.9 million from this fund were used to process fast track amendments and new products.

During FY 2008, the Agency's obligations charged against the Reregistration and Expedited Processing Fund for the cost of the reregistration and registration review programs and other authorized pesticide programs were $23.5 million and 136.9 work years. Of these amounts, the Agency obligated $22.0 million of this cost and funded the 136.9 work years. The Fund has two types of receipts: fee collections and interest earned on investments. Of the $22.1 million in FY 2008 receipts, approximately 99% were fee collections.

Appropriated funds are used in addition to Reregistration and Expedited Processing Fund dollars. In FY 2008, the Enacted Operating Plan included approximately $38.6 million in appropriated funds for reregistration and registration review program activities. This supported 214.9 work years and $11.2 M in contract support which included data reviews, systems maintenance and enhancements and other expenses. The unobligated balance in the Fund at the end of FY 2008 was $6.6 million.

PRIA and Pesticide Worker Protection

Under FIFRA Section 33(c)(3)(B), EPA is authorized to use 1/17 of the amount of the Fund (but not less than $1 million) to enhance current scientific and regulatory activities related to worker protection and approximately, $500,000 in each of fiscal years 2008 through 2012 for funding of the Pesticide Safety Education Program (PSEP).

The Agency worked closely with worker safety stakeholders through the Agency's Federal Advisory Committee, the Pesticide Program Dialogue Committee (PPDC), to determine which activities to enhance with PRIA funds. Based on the advice of the PPDC, the Agency decided to develop enhancements within the following focus areas: Prevention - Safety Training, Response - Poisoning Recognition, Sound Decision Data, and Inform - Risk Management. Table I (PDF, 6pp, 60.46k) lists the activities funded in FY 2008.

PRIA and Partnership Grants

When PRIA was reauthorized, an amount from the fees collected were set aside for partnership grants in Section 33(c)(3)(B)(ii); specifically $750,000 each for fiscal years 2008 and 2009 and $500,000 each for fiscal years 2010 through 2012. In 2008, EPA augmented these funds with appropriated funds and awarded $1 million in grants to fund five projects that use Integrated Pest Management (IPM) approaches to reduce pesticide risk. The grants were provided to advance public-private partnerships that focus on stewardship efforts that result in reduced risk associated with the use of pesticides. These grants support the demonstration of innovative IPM practices and technologies, as well as outreach and education, in California, Florida, Wisconsin, and Michigan. The recipients were:

- California Department of Pesticide Regulation: $159,494 for "Reducing Volatile Organic Compound Emissions from Pesticide Use in Nuts and Tree Fruit Orchards in California's San Joaquin Valley"
- IPM Institute of North America: $250,000 for "High-level IPM in All U.S. Schools by 2015"
- University of Florida, College of Agriculture and Life Sciences: $246,418 for "Reduced Pesticide Use for Bermisia tabaci and Greenhouse Whiteflies [GHWF] on Greenhouse Tomato using Protected Culture, IPM Techniques, Parasitic Wasps, and Papaya Banker Plants"

- Michigan State University: $91,508 for "Increasing Adoption of Reduced-Risk Pest Management Practices in Midwest Blueberries to Prepare for FQPA Implementation"
- Central Coast Vineyard Team: $225,000 for "Reducing Pesticide Risk through the Adoption of Integrated Farming Practices in Central Coast Vineyards and Marketing Certified Sustainable Products".

These projects began at the end of FY 2008 after a competitive selection process.

The 2009 Request for Proposals and PRIA 2 Partnership Grants competition is targeted for early February 2009. For FY 2009, EPA intends to award a total of $1 million, with PRIA 2 funds supplemented by an additional $250,000 from EPA's Office of the Science Advisor. Additional information is available on the PRIA 2 Partnership Grants website.

Progress in Meeting Decision Times

Number of PRIA Actions Completed in FY 2008

The Agency completed 1677 decisions subject to PRIA during the fiscal year, 57 (3.5%) more than the 1620 reported in the FY 2007 annual report. Among the FY 2008 completed decisions, 336 (20% of total) were antimicrobial decisions, 98 (5.8%) biopesticides and 1243 (74.1%) conventional pesticide decisions. In comparison, of decisions completed in FY 2007, 308 were antimicrobials, 123 were biopesticides, and 1189 were conventional pesticide decisions. The numbers of antimicrobial and conventional completions increased slightly while the number of biopesticide decisions decreased by 20%. An additional 156 decisions were withdrawn (22 antimicrobial, 10 biopesticides and 124 conventional) while in FY2007, 136 decisions were withdrawn with 35 antimicrobial, 24 biopesticides and 77 conventional decisions withdrawn.

EPA completed 99.9% percent of these decisions on or before their PRIA or extended due date. One action missed the statutory due date due to a change in the fee category to one with a shorter time frame, leaving little time to meet the new due date.

Table II (PDF, 11pp, 186k) titled "Number of PRIA Actions Completed in FY 2005 …and 2008", summarizes the number of decisions completed by PRIA category and compares FY 2005, FY 2006, FY 2007 and FY2008. FY 2005 was the first full fiscal year under PRIA. Actions received under both PRIA 1 and PRIA 2 were completed and both types of fee category codes are shown. Actions with a fee category with two digits are PRIA 1 actions (e.g., R01, A53) and PRIA 2 actions have a three digit fee category (e.g., R010, A530). In reviewing the table, certain factors need to be considered. An application can have more than one decision. The number of decisions depends on the number of product registrations in an application. If a tolerance petition is included in the application, the petition is also assigned a decision number to allow the Agency to track it and assure that it is completed by the PRIA due date for the application. For instance, in FY 2008, one new conventional active ingredient was registered that had six decisions consisting of one for the tolerance petition and five products. Information on the number of active ingredients and uses registered each year can be found in the Office of Pesticide Program's Annual Reports. Generally each application categorized as a Fast Track, Non-Fast Track New Product, identical/substantially similar new product, new product, Non-Fast Track Amendment or label amendment submitted with data, contains a single product and is a single decision.

The number of actions (or decisions) completed each year has increased steadily by over 20% per year from FY 2005 through FY 2007. However the number completed in FY 2008 was only 3.5% higher than FY 2007, an indication that applications have leveled off. Only eight more applications were received in FY 2008 than in FY 2007. In comparing completions in FY 2008 with FY 2007, there were 19 more conventional new active ingredient decisions; 64 more conventional new use decisions; and 26 more decisions completed in the new PRIA 2 fee categories. There were 60 fewer new products completed in FY 2008, with the largest decrease among the conventional new products (-47).

The average decision time for each PRIA category is shown in Table II and is the number of days it took the Agency to complete a decision once payment was made or a fee waiver or exemption was granted. The time frames mandated under PRIA 2 generally remained the same as under PRIA 1 for similar fee categories. Exceptions were a reduction in the time frame for conventional reduced risk pesticides and an increase in the timeframe for biochemical new products that required more than product chemistry data. For instance, the time frame for a reduced risk food use new conventional active ingredient decreased from 21 months to 18 months, while a non-reduced risk new conventional active ingredient's time frame remained 24 months. Under PRIA 1, time frames did decrease from one fiscal year to another, e.g., for an R17 the time frame in FY 2006 was 22 months and it was reduced to 15 months for FY 2007 and FY 2008. A decision's time frame is based on the fiscal year in which the application was received. The dates that decisions completed in FY 2008 were received ranged from prior to PRIA (voluntary payments) to 2008 resulting in decisions completed within one fee category with different mandatory time frames. Consequently, the average decision time or the number of days the Agency took to complete a decision, in the table can not be directly compared to the PRIA time frames mandated for FY 2008.

In reviewing average decision time frames for similar PRIA 1 and 2 fee categories, the average decision review time frames for PRIA 2 decisions were lower, particularly for conventional amendments and new products requiring more than product chemistry data and for antimicrobial actions. Whether this is due to the new PRIA 2 fee categories created for applications that were difficult to complete in their PRIA 1 mandated time frames, cannot be predicted at this time. A small number of decisions were completed in these PRIA 2 fee categories and additional data are needed to be able to make reliable comparisons.

Average decision times for conventional new uses and amendments requiring review in science divisions deceased in FY 2008 from FY 2007. Average decision times for new active ingredients increased from FY 2007. As discussed in past annual reports, average decision times for new active ingredients were expected to increase as new active ingredients that had benefited from work completed before March 2004 were completed and a greater number of new applications were completed. In the FY 2007 report, the average decision times for reduced risk new food use active ingredients and new food uses were greater than those of non-reduced risk decisions. The number of reduced risk decisions was too small for us to conduct an adequate analysis in 2007. In FY 2008 the average decision times for reduced risk new active ingredients were lower than those for non-reduced risk decisions.

Among the FY 2008 completions, due dates for 306 (18%) decisions were extended by mutual agreement of the applicant and the Agency. The percentage of decisions completed with due date extensions has increased each fiscal year. During FY 2006 and FY 2007, 11% and 13% of due dates, respectively, were extended. Extensions generally resulted from missing or deficient data or information. Due dates were extended for 14.9% of completed conventional decisions, while in the previous fiscal year, 7% were extended. Twenty-two percent of antimicrobial and 48% of biopesticides were extended, similar to 2007 (25% and 42% respectively). The number of due date extensions among decisions in conventional (R) fee categories more than doubled and accounted for the increase in the number of completed actions with a due date extension.

	FY2007		FY2008	
Fee Category	**Number completed decisions with due date extension**	**Total completed**	**Number completed decisions with due date extension**	**Total Completed**

Antimicrobial (A)	77	308	74	336
Biopesticide (B)	52	123	47	98
Conventional (R)	78	1189	185	1243
Total Decisions	207	1620	306	1677

Of the 306 decisions with due date extensions, 142 were new product decisions, 29 new active ingredients, 94 new uses, 31 amendments and 10 other types of decisions. In FY 2007, the number of decisions with a due date extensions were 121 new products, 28 new active ingredients, 18 new use, 35 amendments, and 5 other types of decisions.

Of the due date extensions in the different types of fee categories, new active ingredients, new uses, etc, new active ingredients continued to have the highest percentage of extended due dates. Of the new active ingredient decisions completed in FY 2008, 38% had extended due dates, which is similar to FY 2007. In FY 2007, 19% of completed non-fast track new product decisions had extended due dates. A common reason for these extensions was product chemistry data deficiencies. In FY 2008, an increased percentage of new product decisions (23%) other than fast track new products had extended due dates. The percentage of new use completions with due date extension increased substantially in FY 2008 (27%), compared to FY 2007 (7%) due to the time required to resolve risk issues. A smaller percentage of completed 3 month Fast Track New Products (7.5%), and amendments (8.4%) had due date extensions and approximately the same as FY 2007.

Note: Appendix A contains a list of all applications subject to PRIA reviewed during FY 2008 (Excel, 287 KB) and includes the decision times for each application. (Microsoft Excel Viewer EXIT Disclaimer is needed to view this file.)

Under Section 33(k)(2)(A)(iv), the Agency is to report the number of applications completed for identical or substantially similar applications under section 3(c)(3)(B), including the number of such applications completed within 90 days pursuant to that section. There are two types of identical or substantially similar applications, new products and label amendments that require no data review. The former have been called in the past "Fast Track New Products" while the label amendments are still called "Fast Track Amendments".

Identical or substantially similar new products (formerly "Fast Track New Products") are subject to registration service fees and have mandated decision review time frames under PRIA. With the passage of PRIA 2, identical or substantially similar products or Fast Track New Products were further subdivided into additional fee categories, some of which have time frames greater than three months. The number of identical or substantially similar products with a three month time frame (A53, A530, B66, B660, B71, B710, R30, and R300) completed in FY 2008 was 358 of which 331 were completed within their PRIA time frames and the remainder had due date extensions. An additional 37 identical or similar new products with time frames of greater than three months were completed (34 within the time frame and 3 with due date extensions).

The time frame for "Fast Track Amendments" remained 90 days under PRIA 2 and these amendments are not subject to registration service fees. In FY 2008, the Agency completed 2526 fast track amendment decisions or actions (unaudited results - antimicrobial 999, biopesticide 140, and conventional 1387) which had 2909 submissions (1049, 185, and 1675, respectively). Each decision can have a number of submissions, each with a time frame of 90 days. Of these submissions, 2500 were completed within 90 days (1007, 148, and 1345, respectively).

Section 33(k)(2)(E) directs the Agency to review its progress in meeting the timeline requirements for the review of antimicrobial pesticide products under section 3(h). The timeline requirement under section 3(h) for substantially similar or identical products is 90 days. Of the 70 decisions in fee categories A53 and A530, 56 (80%) were completed within 90 days and 59 (84%) completed within the three month PRIA time frame. The remaining 11 had due date extensions and were completed in 118 to 291 days. All 16 other substantially similar or identical products in fee categories A531 and A532 were completed within their PRIA time frame of 4 months and 8 of these decisions (50%) were completed within 90 days. Regarding other new product decisions in fee categories A54, A540, A55, and A550, the section 3(h) time frame is 180 days with a goal of reducing the review time to 120 days. Of the 76 decisions in these fee categories, all met their PRIA due dates or extended due dates and 35 (46%) were completed within 120 days and 45 (59%) completed within 180 days. Of the remaining 31 decisions, 30 were PRIA 1 decisions with an extended due date into FY 2008. The number of days to complete these PRIA 1 actions ranged from 185 to 641 days.

Number of PRIA Applications Pending at the End of FY 2008.

Table III (PDF, 9pp, 156k) summarizes the pending registration applications (counted as decisions) in each of the PRIA categories. As of September 30, 2008, 1129 applications subject to PRIA were pending in the Agency's registration queue. Numbers pending at the end of FY 2007, 2006 and 2005 are shown for comparison. The number of applications received in FY 2008 was approximately the same as FY 2007 as previously mentioned. Consequently, the decrease in the number pending at the end of FY 2008 from FY 2007 was due to the slight increase in the number of decisions completed and withdrawn.

The total number of applications (counted as "decisions") received in FY 2008 was not affected by the passage of PRIA 2 or the increase in fees and fee categories. Shifts however, were observed in the types of applications received between FY 2007 and FY 2008. Fourteen additional new active ingredient decisions and 77 amendment requests were received, along with approximately 78 actions in other categories, some of which were created by PRIA 2. Fewer new product (-148), new use (-7), and emergency exemption (-6) requests were received in FY 2008.

The number of antimicrobial decisions pending in FY 2008 was greater than FY 2007 (179 versus 157), reflecting increased receipts (382 versus 330). More new use (+23) and amendment (+31) requests were also received.

The pending number of biopesticide decisions was higher in FY 2008 (127 versus 91), while receipts were only slightly down (137 vs. 146). The increase in number pending was due to a decrease in the number of decisions completed, particularly amendments (13 completed in 2008 versus 30 in 2007) and new products (48 vs. 60). The increase in the number of pending new active ingredient decisions at the end of FY 2008 was due to a combination of increased receipts and decreased completions.

Among conventional pesticide decisions, the number pending at the end of FY 2008 was less than at the end of FY 2007 (823 versus 959). Conventional completions increased (1243 vs. 1189), withdrawals increased and receipts decreased by less than 3% resulting in the decreased number pending at the end of FY 2008. There were differences in the types of conventional pesticide applications (counted as "decisions") received between FY 2008 and FY 2007. Fewer new product decisions (-124) and new use decisions (-23) were received. New product decisions have shorter time frames and the decrease in 2008 receipts resulted in a decrease in the number completed and the number pending at the end of FY 2008. There was a slight increase in the number of amendments (+41) and new active ingredients (+9) decisions received. Decisions in the new PRIA 2 categories (+60) included 19 protocol reviews and 32 tolerance amendments.

Pending Inert Ingredient Reviews at the End of FY 2008

FIFRA section 33(k)(2)(F) requires EPA to provide the number of inert ingredients (inerts) pending review

by the Agency. In FY 2008, 4 new petitions for a food use inert were received as PRIA actions and an additional 26 new petitions were received as non-PRIA 2 actions. When PRIA was reauthorized, a request to approve an inert submitted with an application to register a conventional new product became subject to registration service fee requirements.

In FY 2008, 13 Final Rules were published; 3 petitions were denied; 14 petitions were withdrawn due to deficiencies; and 1 petition was rejected. At the end of FY 2008, there were 59 petitions in the review queue, which included 17 petitions with deficiencies and 41 in various stages of review. One petition was rejected due to major deficiencies. All inerts petitions are scheduled for review in the order received on the workplan. The Agency estimates that the average review time is 3-6 months for a polymer exemption petition and approximately 12 months (including data review, science assessment, decision document, and Final Rule) for a new inert petition. All new petitions are screened for deficiencies before being scheduled for review, and EPA works with prospective petitioners to discuss the reliability and adequacy of the data to meet the FQPA safety finding. In addition, twenty-seven non-food use requests were granted and 12 non-food requests were pending at the end of FY 2008.

The Inert Ingredient Assessment Branch (IIAB), consisting of seven employees at the end of FY 2008, reviews inerts actions. During the year, the Branch lost one employee and added three. When needed, IIAB staff are supplemented with staff in other pesticide regulatory groups, particularly to review inert ingredients associated with biopesticide and antimicrobial products.

Process Improvements in the Registration Program

Section 33(e) of FIFRA directs EPA to identify and evaluate reforms to the pesticide registration process with the goal of reducing decision review times for pesticide registration applications. Section 33(k) directs the Agency to report its recommendations for process improvements in the handling of and streamlining registration review. The Agency has made considerable progress during the fiscal year in improving its operations. A number of steps were undertaken, internal and external, to explore, develop, and implement improvements in the registration and registration review processes.

In improving processes, the Agency will not compromise the scientific quality of its assessments as a means toward reducing decision times. The Agency believes that the best means of gathering recommendations for process improvements is through the Federal Advisory Committee Act (FACA) process.

Pesticide Program Dialogue Committee PRIA Process Improvement Workgroup

The PRIA Process Improvement Workgroup was created in FY 2004 under the auspices of the Agency's Federal Advisory Committee, the Pesticide Program Dialogue Committee, to evaluate process improvements for the registration program. The workgroup is composed of members from pesticide registrant companies, pesticide trade associations, public interest groups, and Agency staff. Meetings are open to the public and are held approximately 2 to 4 times a year. Reports of the April 29 and September 23, 2008, PPDC PRIA Process Improvement Workgroup meetings are posted on the internet.

Industry stakeholders identified many areas for improvement in the registration and registration review process, including labeling consistency, communication of schedules, use of electronic tools, application and submission guidance, and efficiencies in product reregistration and registration review. Many of the process improvements implemented by the Agency have addressed these issues. The Agency continues to work with all stakeholders to evaluate potential improvements to the registration and registration review processes. During Workgroup meetings, stakeholders present their priorities for process improvement and the Agency discusses the status of its improvement projects; previews new tools and proposed changes in procedures and processes; presents analyses of specific processes; and reports on its

successes. Future projects and efforts are identified through a dialogue between the Agency and stakeholders.

Electronic Submission and Document Retention

The Agency is conducting a number of efforts to use information technology to improve the efficiency of the pesticide registration program and reduce the paperwork burden on both the Agency and the public.

In July 2008, EPA's Office of Pesticide Program announced it would receive pesticide submission packages in electronic form or e-Registration submissions following a pilot project conducted in FY 2007. EPA published a Federal Register Notice and provided guidance on the Web to broadcast this initiative. The types of applications currently being accepted electronically are Section 3 New Applications, Section 3 Amendments, Experimental Use Permits, Petitions for Tolerances, and applications for Supplemental Distributor Products. The Agency also established an e-Submission Help Desk in May 2008 to assist applicants with their questions about formatting their e-submission and to provide step-by-step direction to ensure the validity of the submission.

The e-Submission Module of PRISM supports the processing of the voluminous documentation required for pesticide applications. Traditionally, this paperwork has been submitted in hardcopy form. The E-Submission initiative helps EPA move toward a more paperless environment. The information exchange from industry to EPA is based on a harmonized XML schema adopted from Canada's Pest Management Regulatory Agency (PMRA). This harmonization assures that a submission package submitted to one participating regulatory agency can likewise be submitted to any of the other participating agencies, thus increasing standardization and decreasing the burden on pesticide applicants. Once the package is received by EPA, its contents are parsed and validated, thereby promoting data quality. The data submitted are then used to pre-populate data entry screens in an effort to save processing time and decrease the burden on EPA. Finally, the e-Submission module is fully integrated with PRISM's core data repository for registration information and its document management repository. When the incoming package has been processed within e-Submission, the data and documents are seamlessly blended into other PRISM components (Document Management Workflow) for processing within the pesticide programs. PRISM was enhanced to accept electronic registration (e-Registration) documents to make these documents available on-line at any time to the multiple users simultaneously processing registration actions. E-Submission/e-Registration will improve processing times, data quality and completeness; reduce data entry and the number of data entry iterations; and improve document management.

To facilitate the 21 day initial content review, a Workflow Management tool, was developed for the registration program that notifies the 21-day screening teams and staff that e-Registration documents are available on line for their review. This feature allows the teams and staff to work collaboratively with all electronic documents on line.

By scanning documents and storing e-Registration documents, a Documentum library of over 150,000 Studies is available electronically. The user friendliness of the application was increased by upgrading the user interface to include improvements such as Basic Searching, Advanced Searching, Categories Search, and the ability to save "My Saved Searches" so users don't need to re-enter the same search parameters over and over.

Electronic Labels

Under PRIA 2, FIFRA Section 33(k)(2), the Agency is required to report the number of label amendments that have been reviewed using electronic means and make recommendations for electronic submission and review of labels, including process improvements to further enhance the procedures used in electronic label review. The Agency and stakeholders recognize that reviewing labels can be time consuming. Electronic Label Review continues to move forward. Use of e-labels has the potential to make label reviews more efficient and accurate. Reviewers use software to compare a label submitted in PDF format to the previous label to quickly identify where changes have been made. The same software can

be used to annotate required corrections, if any. The marked-up label can be e-mailed to the registrant and then the revised label can be e-mailed back to the Agency.

All regulatory staff received training on the software during 2007 with additional training sessions in 2008. Adoption by staff is increasing although the exact level is unknown at this time. The Agency has found that, once users find how easy it is to compare or comment on e-labels, they usually become enthusiastic about the process.

The Agency has encouraged submission of e-labels. The number of e-labels submitted has risen steadily: 174 in 2005, 346 in 2006, 807 in 2007, and 1267 in 2008. This is only a fraction of the total number of labels submitted each year although the percentage of labels reviewed electronically is not known at this time. E-labels can be submitted either on CD-ROM along with a paper application or using EPA's recently implemented e-submission process in which the entire application is delivered on CD-ROM in an XML structured format without any accompanying paper.

During FY 2008, the Agency began an effort to modify its tracking systems to provide the level of reporting required of PRIA 2. Beginning in 2009 OPP will be able to quantify both the percentage of labels received electronically and the number of e-labels reviewed (a count required to be reported annually by PRIA 2). PRISM, EPA's pesticides tracking system, has been modified to record the content of each submission and whether an electronic review was conducted for submissions containing e-labels.

As a next step in improving electronic label submission and review, EPA prepared a comprehensive list of requirements for electronic labels (e-Label). The objective of this effort is to improve the process of reviewing labels electronically and provide a tool for applicants to use in developing their labels. The general premise of the e-label is to identify all label content in a structured manner so that individual label elements can be processed with automated systems. Structured label content is expected to still further improve the efficiency of the label review process, allow for greater consistency of labeling content, and facilitate the distribution of product labeling via the Internet. Based on those requirements, the Agency is developing an XML schema definition that describes the technical specifications for the structured label content. Also under development is an application to load e-labels into the internal data system. The requirements for a "builder" application, to be used to create the needed e-label file, will be identified in the coming months.

Labeling Committee

Both stakeholders and the Agency recognized that labeling issues should be addressed. The Agency formed a cross-program Labeling Committee in FY 2005 to address broad labeling issues and to oversee revisions to the Label Review Manual. A subgroup, the Label Review Manual Team, was formed to revise and continually update the Label Review Manual. During FY 2008 the Team completed its review and drafted revisions to the Manual. All but three of the revised chapters have been posted to the Web and the remaining three should be posted during 2009.

The Committee developed a Web site to communicate its activities and to address the public's labeling policy questions forwarded through the Web site's e-mail address (OPP_labeling_consistency@epa.gov). The Committee received 100 questions during FY 2008 (a total of 226 questions since the site began). Answers to the majority of these questions were posted while some received a direct response. Due to the increase in number of questions and answers, the Agency reorganized the question and answer portion of the Web site. This reorganized Web page will be posted during FY 2009. At the suggestion of stakeholders, the Agency now flags new questions and answers with the word "New" in yellow for 30 days. The date answers were approved by the Agency is now placed next to the associated question. To address concerns that responses being posted on the Web site might result in changes to labels already on the market, the Committee placed a disclaimer at the beginning of the question and answer Web page.

The Committee incorporated labeling recommendations from the Pesticide Program Dialogue Committee's Consumer Label Improvement Workgroup into Pesticide Registration (PR) Notice 2008-1 which was finalized on May 1, 2008. The Committee from time to time publishes issue papers on its Web site. The issue paper published on Chemigation (PDF, 6pp, 63.8kb) was available for comment in December 2008.

Product Chemistry

In FY 2008, analysis of the reasons for PRIA due date extensions continued and again showed that in each of the pesticide registering divisions at least 20% of the due date extensions involved product chemistry issues (including inert issues). The Agency updated or is in the process of updating several internet pages such as for biopesticides to help guide applicants in their product chemistry and inert (PDF 4pp, 236.64k) submissions, with a goal of addressing common errors.

Many common errors are made on the Confidential Statement of Formula (CSF) form on which registration applicants list the contents of a product. The Agency has developed a smart CSF form for applicants to use to complete it. The smart form informs the applicant when a required portion of the form had not been completed or if the percent composition column does not add to 100%. The completed form can then be submitted in an electronic file format which will reduce the Agency's reliance on paper and data entry required of the current paper-based process and make information readily available within the pesticide registration program. This application has undergone two stakeholder usability tests and modified based on comments. The e-CSF will be available on EPA's Web site in FY 2009.

When the source of a conventional active ingredient is changed to a different manufacturer or source, the manufacturing or synthesis process may result in different impurities, which the Agency must assess for potential toxicological concerns. The Agency is in the early stages of developing a formal process involving the human health risk assessors to evaluate these impurities. This change in process arose as a result of an increase in the number of source changes and the additional or other impurities identified in the manufacturing (technical) product.

Inerts

As part of the 21-day screen, Confidential Statements of Formula (CSF) are being reviewed to determine the status of the inert ingredients listed. This review early in the process and follow-up dialogue with Agency staff has resulted in a decrease in the number of inerts issues on CSFs. To help applicants determine whether an inert ingredient is approved for their proposed uses, the inerts Web site is continually updated and an e-mail address (inertsbranch@epa.gov) is available for applicants to request information directly from the Inert Ingredient Assessment Branch staff. Guidance is being drafted on the submission of petitions and inert approval requests. The Agency has drafted requirements for modifications to its pesticide application information tracking system PRISM for inerts petitions and requests which, when implemented, will allow the Agency to track information, monitor progress, and provide information on the status of completed and pending inerts actions.

Process Improvements Implemented within the Pesticide Registration Program

The Agency's success in meeting due dates was a result of its continued monitoring of the status of PRIA decisions and identification of efficiency measures that conserve resources and time. Internal processes and tracking systems were modified to incorporate the new PRIA 2 fee categories and its numbering system, new fees, additional time frames and the 21-day initial content review. All automated reports were then modified to identify applications coming due, late applications, late payments, and to report, for instance, the status of fee collections, rejections and due dates.

Agency staff continue to meet regularly to monitor workload and compliance with PRIA due dates and to resolve fee category and interpretation issues. For instance weekly meetings focus on the status of pending decisions, due date extensions, and refunds; identifying and resolving potential issues; resolving fee category questions; and coordinating schedules with science support organizations. During these meetings, staff identify PRIA 2 implementation issues and then discuss them with senior management to assure consistent implementation across the pesticide programs. They review policy decisions made during PRIA 1 for consistency with PRIA 2. This led to a detailed analysis of the manner in which discretionary refunds were given for applications dependent upon other applications. Inconsistencies in fee categories between A, B and R categories were identified particularly in how applications with an unapproved inert and requests to approve an inert were classified. Guidance resulting from these discussions will be released in FY 2009.

Senior managers continued to review justifications and make final decisions to extend or negotiate a PRIA due date and whether or not to issue a "PRIA Determination to Not Grant" as under PRIA 1. On a bi-monthly basis, progress in meeting PRIA due dates and the short term pending workload are evaluated across all involved organizations and periodically shared with stakeholder groups.

Notifications Process

Although notifications are not PRIA actions, a more efficient notifications process allows more time for PRIA actions. The Biopesticides and Pollution Prevention Division (BPPD) revised its notification review process a second time in 2008. In FY 2007, BPPD's Notification Response Team began to convert unacceptable notifications with minor administrative issues into Fast Track Amendments to save applicants the time and effort required to resubmit the application as an amendment. This process successfully reduced a backlog, but resulted in increasing numbers of actions that had to be converted at an unacceptable cost in BPPD staff time to process changing the notification into an amendment. BPPD revisited this process in FY 2008. The BPPD Notification Response Team now informs the applicant in writing whether the notification is Acceptable or Not Acceptable under PRN 98-10. If it is not acceptable, the applicant must convert the notification into an application for an amendment and then submit it to the Agency.

Science Review Improvements

Ecological Risk Assessments

The Agency continued to improve its review and communication of ecotoxicity studies through the following efforts: joint review/work sharing of study reviews with other countries; harmonization of ecotoxicity endpoints with other EPA programs; identification of critical data needs early in the risk assessment process; publication of peer-reviewed ecotoxicity values; and streamlining the data evaluation of published scientific studies. Examples of these improvements include the following:

- Working with the Organization for Economic Cooperation and Development (OECD), the Agency identified more efficient means to conduct joint reviews and work sharing, thus reducing review times and workload. The Agency also shared technical information with OECD countries and developed joint projects that will further improve the joint reviews of ecotoxicity studies. Examples of these joint projects include the harmonization of the terrestrial field dissipation guidance with OECD and the development of a crosswalk of ecoregions between North America and European countries. The Agency is also beginning to work with China in developing harmonized pesticide risk assessment approaches.

- In the registration review program, the Agency has developed an approach for identifying critical ecological effects data gaps early in the risk assessment process. The Agency has also proposed and implemented scientifically appropriate methods to conduct risk assessments by relying on alternative techniques such as ECOSAR (Ecological Structure Activity Relationships) to estimate

the toxicity of pesticides to aquatic organisms. Using these alternative techniques reduces the workload and review times for the Agency and reduces the testing burden on registrants. If additional data are still needed after using alternative techniques, EPA will request additional testing from the registrants.

- For assessing risks of pesticides to endangered species, the Agency has developed improved exposure and risk modeling tools for terrestrial organisms. Specifically, the Agency has expanded the application of existing models (e.g.,T-HERPS) and approaches to include reptiles and terrestrial-phase amphibians.

- In response to requests from FIFRA state lead agencies and state water quality agencies, EPA developed "benchmark" values for pesticides that can be used to interpret monitoring data and to identify and prioritize sites for further monitoring. The benchmarks, which are based on the most sensitive aquatic toxicity data, are estimates of the concentrations below which pesticides are not expected to harm aquatic life. The Agency has made benchmark values for 70 pesticides available to the public by posting them on its Aquatic Life Benchmark Web site. This Web page will be updated annually with additional aquatic toxicity data used in the Agency's pesticide risk assessments.

- In response to concerns raised by states and other stakeholders, EPA's Office of Pesticide Programs (OPP) continued to work with the Office of Water (OW) to develop a harmonized approach for assessing aquatic toxicity data. OPP and OW have shared data and coordinated the development of ecological risk assessments in OPP with the development of ambient water quality criteria in OW. EPA is planning to sponsor a stakeholder workshop in 2009 to discuss a proposed harmonized approach for assessing aquatic toxicity data.

- In FY 2008, the Agency focused efforts on improving its spatially-explicit risk assessments for aquatic risk and exposure assessments. As part of this effort, the Agency acquired and developed data, including improved soil, land use, and hydrography data –as well as improved tools to provide more accurate and relevant information about the potential effects of pesticides in the environment. These data and tools, which are being used in the Agency's risk assessments, allow EPA to more quickly identify the landscapes and water bodies that are most vulnerable to pesticide impacts on drinking water sources and on aquatic species, including endangered species.

- The Agency enhanced its existing aquatic models (e.g., PRZM-EXAMS) to predict downstream effects of pesticides on aquatic species for use in endangered species assessments. With these enhancements, EPA is able to assess water bodies outside of the normal modeling scenario, such as off-channel habitats outside the stream channel, and to rapidly identify water bodies of concern. In addition, the enhanced models were used in developing mitigation options such as distances for spray drift buffers.

- In the review of public literature, EPA has developed a template for summarizing peer-reviewed published studies. These review summaries are attached to the published studies and stored electronically on the Agency's internal network for easy access by staff, facilitating the assessment and regulatory review processes.

Human Health Risk Assessments

The Health Effects Division (HED) reorganized to accommodate changing work priorities. There are now 7 Risk Assessment Branches that perform both registration and registration review activities. In the past, the four reregistration branches focused on the reregistration program, and three registration Action branches supported registration of new chemicals and uses. With the completion of reregistration, the division refocused on the new registration review program. Instead of work being assigned to a branch based on the type of action (reregistration vs. registration), branch staff will become familiar with all aspects of each assigned chemical. This improves consistency of risk determinations for each chemical since the same branch and team complete all assessments for a given chemical, which are typically done

over a period of years.

The seven HED production branches conduct similar analyses for a final human health risk assessment document. These include evaluations of the various toxicological concerns, chemistry issues, and occupational and residential exposure. This reorganization improves efficiency and improves the Agency's ability to meet the PRIA time frames.

The Toxicology Science Advisory Council (ToxSAC) and Residues of Concern Knowledgebase Subcommittee (ROCKS) continue unchanged and have added robustness and strengthened the science of the HED risk assessments. In calendar year 2008, the Dose Adequacy Review Team (DART) met twice on two chemicals. Inhalation waivers continue to be received and processed by the production branch assigned the individual chemical.

Improvements in human health risk assessment methodologies are being undertaken by the Agency.

- Consistent with the National Research Council (NRC) of the National Academy of Science vision of toxicology in the 21st century EXIT Disclaimer in its 2007 report, EPA is exploring the new emerging tools of computational toxicology to improve its testing and assessment approach where *in vivo* or animal testing would be targeted to the most likely hazards and risks of concern. The approach would be based on integrating existing data, computer modeling, and new in vitro data to more reliably and efficiently predict toxicity and to determine what specific animal tests are required to provide a sound basis to assess potential human health and environmental risks for pesticide chemicals. The proposed tools and approaches are discussed during meetings of the PPDC's 21st Century Toxicology/New Integrated Testing Strategies Workgroup.

- The pesticide program continues its work with EPA's National Health and Environmental Effects Laboratory, National Exposure Research Laboratory, and National Center for Computational Toxicology to advance cumulative risk assessment methodologies by supporting improvements in modeling mechanisms of toxicity and exposure to humans. The research effort on pyrethroids will be reviewed by the FIFRA SAP in June 2009. The Agency further expects to present additional methods and tools to the FIFRA Scientific Advisory Panel (SAP) in 2010.

- An intra-Agency collaborative effort is developing a model to simulate human exposure to a variety of pesticides, pollutants, and contaminants that will improve risk estimates of aggregate (single chemical, multi-route pathway) and cumulative (multi-chemical, multi-route pathway) exposure to humans. This probabilistic model will predict pesticide exposures from numerous sources such as food, drinking water, inhalation, and contact with various surfaces on a day to day basis and to different age groups.

- The Agency is developing improved animal study designs to more reliably and efficiently address risks to children through its proposed enhanced F1 reproductive generation study. The new enhanced F1 generation study will better target and more efficiently address potential toxicity on the reproductive, neurological and immunological systems with the use of fewer animals. It is scheduled to be presented to the SAP in November 2009.

- In addition to evaluating metabolites and degradates and identifying the residues of concern that need to be considered in a risk assessment and tolerance expression, the ROCKS reviews inerts and manufacturing process impurities and other situations where data are limited for potential toxicological concerns. The use of structure activity in combination with laboratory data is being explored to improve the consistency, reproducibility and characterization of these determinations. As other computational tools become available, they will expand the suite of predictive tools available to the ROCKS for its comprehensive review process.

Section 33(k)(2)(A) directs the Agency to report its recommendations for the allowance and use of summaries of acute toxicity studies. To date no acute toxicity summary has been submitted to the Agency for review. However, if submitted electronically it may help in creating a Document Evaluation

Record (DER). Currently, OECD template DERs submitted electronically with new chemical registrations are being used to help develop the Agency's DERs.

Progress in Meeting Tolerance Reassessment and Reregistration Timelines

FY 2008 Accomplishments

During Fiscal Year 2008**,** EPA completed 27 Reregistration Eligibility Decisions (REDs). These were the last risk management decisions for 613 pesticide cases that were subject to reregistration.

Status of Reregistration and Tolerance Reassessment

At the end of FY 2008, EPA had completed risk management decisions for all 613 pesticide cases that initially were subject to reregistration, satisfying PRIA requirements and supporting the Agency's human health and environmental protection goals. Of the 613 reregistration cases, 384 resulted in completed REDs and 229 resulted in voluntary cancellations.

Through the reregistration program, EPA reviewed current scientific data for older pesticides (those initially registered before November 1984), reassessed their effects on human health and the environment, and required mitigation measures as necessary to reduce risks. Pesticides that had sufficient supporting data and whose risks could be successfully mitigated were declared "eligible" for reregistration. RED documents for those pesticides are available on the Agency's Pesticide Reregistration Status Web site. The Agency completed the last of 9,721 tolerance reassessment decisions in FY 2007.

Product Reregistration

Product reregistration is EPA's program for implementing reregistration eligibility decisions by ensuring that required risk reduction measures are reflected on pesticide product labels. At the end of the reregistration process, after the Agency has completed a Reregistration Eligibility Decision (RED) for a pesticide active ingredient and declared it eligible for reregistration, individual end-use products that contain the pesticide active ingredient still must be reregistered.

EPA has completed its review of the safety of pesticide active ingredients first registered before November 1984. The last REDs were completed in FY 2008, and EPA expects to complete product reregistration by 2014. Over 22,500 pesticide products are subject to product reregistration. EPA has completed decisions for almost 9,500 of these products and still must complete decisions for over 13,000 products.

Progress and Goals

During the past several years, as RED production work decreased, EPA has placed increased emphasis on post-RED work and product reregistration consistent with the recommendations of an external review of this program. As a result:

- Having completed just over 500 product reregistration actions in FY 2005 and FY 2006, the Agency completed almost twice as many (979) actions in FY 2007.
- In FY 2008, the Agency exceeded its goal of 1,075 actions and completed 1,197 actions.

EPA's goal is to complete 1,250 actions in FY 2009.

Historical Product Reregistration Decisions

	FY 02	FY 03	FY 04	FY 05	FY 06	FY 07	FY 08
Products reregistered	77	53	78	104	169	529	680
Products amended	51	40	35	63	40	80	205
Products cancelled	186	213	14	342	297	370	309
Products suspended	0	5	0	0	0	0	3
TOTAL	314	311	127	509	506	979	1,197

REDs with Product Reregistration Decisions Completed

At the end of FY 2008, EPA had completed product reregistration decisions for 184 REDs (out of a total of 384). These 184 REDs included 23 of the 31 organophosphates (OPs). Five of the eight OPs that had not yet completed product reregistration were only awaiting final cancellation orders.

External Review of the Product Reregistration Process

The Agency conducted an external review of the product reregistration process during FY 2006 and FY 2007 to identify potential opportunities for innovation and streamlining in order to ensure timelier implementation of the mitigation measures required in the RED. A link to the external review document, "Evaluation of the U.S. EPA Pesticide Product Reregistration Process: Opportunities for Efficiency and Innovation" (March 2007) is available on the Agency's Product Reregistration Web page.

The external review found that the average time from RED signature to product reregistration decision was 54 months:

- 40 months from RED signature, through batching, DCI approval, DCI issuance, data generation, data submission, to data and label reviews package sent within the Agency to the registering division;
- 14 months from receipt of package by the registering division, through label revisions with the registrant to label approval and product reregistration.

The external review identified sources of delay:

- Unresolved issues in signed REDs
- New data submitted to rebut RED conclusions
- EPA's historical focus on RED completion to meet statutory deadlines
- Lengthy post-RED DCI justification process
- Lack of an integrated tracking system for product reregistration
- Breakdowns in internal communication

- Duplication of label reviews within EPA
- Failure of EPA to use suspension authority to ensure timely responses
- Inadequate resources allocated to product reregistration

In response to the external review, EPA initiated several significant streamlining efforts.

- The batching process was streamlined for 2,4-D's 603 products resulting in more than a 50% reduction in the number of product-specific acute toxicity studies required.
- The transfer of the final, reviewed, product package from reregistration to registration was streamlined resulting in significant time savings.
- Instead of trickling packages to registration staff on a product-by-product basis, packages are transmitted from reregistration to product registration only when 95% - 100% of the products are ready.
- An expedited mitigation on labels effort was piloted with propanil, resulting in 40 out of 43 labels being amended with the RED-specified mitigation within 5–8 months after the RED was signed.

In addition, the Agency is following up on recommendations of the external review, especially:

- Implement mitigation in an expedited manner (i.e., immediately after a RED is signed, require amended labels that incorporate the mitigation required in the RED) when it is cost-effective based on the level of mitigation required by the RED
- Pursue additional regulatory action when registrant is in non-compliance
- Expand streamlined batching efforts to other REDs with industry taskforces
- Incorporate quantitative performance goals for product reregistration into performance standards for all managers and staff in participating divisions.

Status of Registration Review

Under PRIA 2, maintenance fees may be used to support registration review, the Agency's process for reevaluating each pesticide every 15 years. With the conclusion of tolerance reassessment and reregistration, the Agency's resources devoted to registration review could be increased. Substantial progress was made in FY 2008. EPA opened 64 dockets for public comment and determined that 7 cases were not to be subject to registration review because the active ingredients involved were no longer registered as an active ingredient. Opening a docket initiates the registration review process for a pesticide case by requesting comments on the information available on a pesticide case. Based on the information submitted in response to request for public comment, the Agency develops a workplan to complete the reevaluation process. The Agency developed 47 final work plans by the end of FY 2008. Schedules for subsequent fiscal years are available on the EPA's registration review web site.

Section 33(k)(2)(D) also requires that the Agency report its recommendations for process improvements in the handling of registration review under Section 3(g) and for streamlining the registration review process. The Agency implemented a number of registration review improvement projects. For instance, the Agency has established a team which follows a standardized process to review and justify Data Call-Ins (DCI) for registration review. The need for each data requirement proposed for each chemical case is judged against a set of standard questions, and only those for which there are satisfactory answers are included in the DCI. To ensure consistency, a library of core justifications for commonly required guideline studies has been compiled from which customized chemical-specific rationales can be developed. These efforts have led to a reduction in the total number of data requirements deemed necessary for registration review, higher-quality data requirement justifications, which follow consistent logic across chemicals, and more efficient production of Data Call-In packages, which are sent to the Office of Management and Budget for approval.

The Agency formed a panel to peer review registration review Summary Documents and Preliminary Work Plans before they are placed in the public docket. The panel's goals are to ensure that workplans are consistent with Agency policy, and that they provide a complete and clear description of the Agency's planned risk assessments and data needs for each chemical case. The panel also recommends process

changes to improve the public's ability to use these documents and to ensure full compliance with the 15-year review schedule mandated under PRIA 2.

In addition, a PRISM e-Registration Review interface module was launched in FY 2008, which consolidates workflow tracking, allows multiple databases to be accessed, and manages documents associated with actions under registration review. Through e-Registration Review, the structure and protocol of managing a chemical case is standardized. All pertinent and historical information (i.e., summary document, work plans, risk assessments, and decision documents) and peripheral documents (e.g., petition, FOIA requests) are in one location for easy access resulting in improved decision-making and a more efficient process.

Other Activities

Use of Outside Reviewers

During FY 2008, the Agency continued its work sharing efforts with Canada's Pest Management Regulatory Agency (PMRA), the Australian Pesticides and Veterinary Medicines Authority (APVMA), and the European Union (EU). In joint reviews, EPA makes its own registration decision while sharing the study reviews and the risk assessment work and harmonizing its regulatory decisions with other national authorities.

In FY 2008, the joint review/work sharing effort produced three new active ingredient registrations for conventional chemicals, and ten minor use actions were completed as part of the NAFTA joint review program. EPA also continued working with the California Department of Pesticide Regulation (CDPR) to expand capacity to review residue chemistry studies and conduct dietary risk assessments in support of registration decisions. In FY 2008, CDPR reviewed the residue chemistry studies for five active ingredients and a total of 31 representative commodities or crops.

Currently, two new active ingredients (conventional chemicals) are being jointly evaluated either by EPA and PMRA under NAFTA, or by NAFTA and the EU. Approximately 17 new active ingredient registration applications (12 conventional chemicals, 4 biopesticides and 1 antimicrobial) are expected to be submitted under the joint review program within the next 2 years. In addition, submissions are expected requesting expansion of the use of two active ingredients that initially were reviewed under the joint review program. Fifteen active ingredient minor use chemicals are expected to be evaluated under the NAFTA joint review program in 2009-2010.

Performance-Based Contracts

Contractors tasked with the review of hazard and exposure data continued to assist the Agency in the selection of endpoints and characterization of hazards for human health and ecological risk assessment. These contractor services enhanced the production of the Agency's risk assessments. The level of contractor support in FY 2008 was generally the same as in FY 2007. Additional contractor support was provided for enhancements in the Agency's database and tracking systems to implement PRIA 2 and for the review of efficacy data and testing protocols.

During FY 2008, approximately 80% of the Pesticide Program's active contracts or work assignments were performance based, an increase from FY 2007. Performance based contracts tend to be contracts with routine and predictable work assignments. Areas covered by these contracts include information management, records management, on-site computer leasing and support, outreach, and as appropriate, data review and risk assessment.

Appendix A: Decision Review Times for Actions Completed During FY 2008

As required by FIFRA Section 33(k), the following table (an Excel file) provides the decision times for each decision (application) during FY 2008. Decisions with a two digit PRIA code are PRIA 1 decisions while those with a three digit PRIA code are PRIA 2 decisions. Decisions received by the Agency on or after October 1, 2007, are PRIA 2 decisions. Decision times indicated in red with an asterisk are decisions completed before the Agency received payment or a waiver was granted. Completion of a registration action before payment is received typically occurs in situations where a voluntary fee payment has been offered for an application that was pending with the Agency prior to March 23, 2004 (the PRIA effective date), or the Agency anticipates approval of a fee waiver based on past fee waiver approvals during the same maintenance fee cycle.

Mandatory decision time frames depend on the year the application was received. Mandated time frames can be found in the fee schedules published in the Federal Register Notice on March 17, 2004, titled Pesticides; Fees and Decision Times for Registration Applications for PRIA 1 actions and on October 30, 2007, titled Pesticides; Revised Fee Schedule for Registration Applications for PRIA 2 decisions**.** The Agency's target due date for completing a decision or action is based on 30 days in a month. The time frames specified in the Consolidated Appropriations Act of 2004 are in months. In the table, if the PRIA due date was met, while the Agency's target date was not, a date was entered in the column labeled PRIA Due Date. As EPA improves its reporting capabilities, the Agency may update this table, as necessary.

Table of completed actions for FY 2008 (Excel, 276 KB) (Microsoft Excel Viewer EXIT Disclaimer is needed to view this file.)